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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,463	05/02/2001	Michael J Tisdale	PM 275915	9962

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EXAMINER
SNEDDEN, SHERIDAN

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/11/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/701,463	TISDALE ET AL.	
	Examiner	Art Unit	
	Sheridan K Snedden	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-59* is/are pending in the application.

4a) Of the above claim(s) *50-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 May 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election of invention I, claims 31-49 is acknowledged. Claims 50-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12. Claims 31-49 are pending.

Claim Objections

2. Claim 45 is objected to because the steps of the process are not clearly separated. Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP 608.01(i)-(p).

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 as Figure 1 and description thereto does not reference the sequence listing. Applicant is reminded of the following:

> *§1.821 Nucleotide and/or amino acid sequence disclosures in patent applications.*
> **(a)** Nucleotide and/or amino acid sequences as used in § § 1.821 through 1.825 are interpreted to mean an **unbranched sequence of four or more amino acids** or an **unbranched sequence of ten or more nucleotides**. Branched sequences are specifically excluded from this definition. Sequences with fewer than four specifically defined nucleotides or amino acids are specifically excluded from this section.
> **(d)** Where the **description** or **claims** of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, **reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:"** in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth below. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive. Appropriate correction is required.

Drawings

3. This application has been filed with informal drawings that are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 101

4. Claims 31 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. As stated, the claims recite a peptide of natural origin and do not show the hand of man. Applicant is advised to include the words "isolated" or "purified" in the recitation of the invention directed towards protein to indicate the hand of man.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention is directed to a lipid mobilizing factor (LMF) and method of making LMF and method of using LMF. LMF is described in the specification as possessing the physiochemical properties of Zn-α^2-glycoprotein. However, the specification fails to teach how to distinguish LMF from Zn-α^2-glycoprotein, and thereof fails to teach how to make and use a LMF different from Zn-α^2-glycoprotein. For example, on page 5, lines 10-15, the LMF is described as Zn-α^2-glycoprotein or are very close analogues and may be referred to as glycoproteins of the Zn-α^2-glycoprotein type. Page 3, lines 25-26, the specification teaches that the composition of human Zn-α^2-glycoprotein can vary somewhat when isolated from different fluids or tissues. Page 28, teaches that antibody raised to Zn-α^2-glycoprotein was capable of detecting the LMF of the instant invention. In this manner, the specification describes the LMF in a way that would suggest that LMF is Zn-α^2-glycoprotein and that the two are one in the same. A LMF other than Zn-α^2-glycoprotein, and variants of Zn-α^2-glycoprotein known in the prior art, is not taught.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of SEQ ID NO: 1 and Zn-α^2-glycoprotein itself, the skilled artisan cannot envision the detailed chemical structure of the encompassed LMF, or variants and fragments which would posses the lypolytic activity, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated proteins comprising the amino acid sequence set forth in SEQ ID NOs: 1 & 2, but not the full breadth of the claim, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32, 33 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The term "substantially" in claims 32, 35 and 39 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not

provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

8. Claims 33 indefinite as they depend from the above claims and do not clarify the ambiguity.

9. Claim 34 is indefinite as the claim recites a protein having homology to the amino acid sequence of SEQ ID NO: 1 but fails to provide a sequence for comparison. The term "homology" would be a relative term. The term "homology' is not defined by the claim and the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

10. Claim 35 is indefinite as the claims recites closed language, "consisting essentially of", followed by open language, having homology to a sequence. The scope of the claims in indefinite.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 31-43 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Araki *et al.* (Proc Natl Acad Sci U S A. 1988 Feb; 85(3):679-83). Araki *et al.* teach Zn-α^2-glycoprotein that shares a 100% homology of with SEQ ID NO: 1 of the instant application(see figure 1). Araki *et al.* teach Zn-α^2-glycoprotein shows a molecular mass of about 39 kDa or about 43 kDa

as is recited in the claims. Claims 31-43 are directed to a lipid-mobilizing agent that has the characteristics of Zn-α2-glycoprotein and the claims recite inherent characteristics of Zn-α^2-glycoprotein as limitations. Specifically, the claims recite the limitation of molecular mass or greater that 6 kD or about 43 kD, lypolytic activity, homology of SEQ ID NO: 1 or of a Zn-α^2-glycoprotein, activity of stimulating adenylate cyclase activity, and immunological properties (regarding claims 31, 32, 34, 35, 36, 38, and 39). Zn-α^2-glycoprotein is a lipid mobilizing factor that has the same electrophoresis mobility, immunoreactivity and ability to stimulate lipolysis and adenylate cyclase activity as Zn-α^2-glycoprotein. In effect, the lipid mobilizing factor recite in the above claims is Zn-α^2-glycoprotein as described in Araki *et al.* and the limitations of claims 31, 32, 34, 35, 36, 38, and 39 are directed to inherent properties of Zn-α^2-glycoprotein.

In addition, Araki *et al.* teach the enzymatic digestion of Zn-α^2-glycoprotein with trypsin, chymotrypsin and pyroglutamte aminopeptidase which would possess the inherent activity or inactivity as described in claims 37, 40, 41 and 43. Araki *et al.* also teaches the purification of Zn-α^2-glycoprotein, which would be "substantially" free of proteolytic activity (regarding claim 42). The ability of periodate treatment to destroy the lipid mobilizing activity is inherent to Zn-α^2-glycoprotein. Thus, the reference anticipates the claimed invention.

13. Claims 31-43 and 45-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohkubo *et al.* (Prep Biochem. 1988;18(4):413-30.). Ohkubo *et al.* teach Zn-α^2-glycoprotein that would shares a homology with SEQ ID NO: 1 of the instant application and would have the physiochemical properties of a Zn-α^2-glycoprotein. Ohkubo *et al.* teach Zn-α^2-glycoprotein shows a molecular mass of about 43 kDa as shown in figure 2 (See also page 419). Ohkubo *et*

al. teach a 6 step purification process that resulted in purified Zn-α^2-glycoprotein in 20mM Tris-HCl buffer, a pharmaceutically acceptable formulation for injection (see page 419, column 2; regarding claims 46 and 47). Claims 31-43 are directed to a lipid-mobilizing agent that has the characteristics of Zn-α2-glycoprotein and the claims recite inherent characteristics of Zn-α^2-glycoprotein as limitations. Specifically, the claims recite the limitation of molecular mass or greater that 6 kD or about 43 kD, lypolytic activity, homology of SEQ ID NO: 1 or of a Zn-α^2-glycoprotein, activity of stimulating adenylate cyclase activity, and immunological properties (regarding claims 31, 32, 34, 35, 36, 38, and 39). Zn-α^2-glycoprotein is a lipid mobilizing factor that has the same electrophoresis mobility, immunoreactivity and ability to stimulate lipolysis and adenylate cyclase activity as Zn-α^2-glycoprotein. In effect, the lipid mobilizing factor recite in the above claims is Zn-α^2-glycoprotein as described in Ohkubo *et al.* and the limitations of claims 31, 32, 34, 35, 36, 38, and 39 are directed to inherent properties of Zn-α^2-glycoprotein.

Art of Record

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Hirai *et al.* teaches that the lipid mobilizing factor of the prior art has the same electrophoresis mobility, immunoreactivity and ability to stimulate lipolysis and adenylate cyclase activity as Zn-α^2-glycoprotein.

Conclusion

14. No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
March 10, 2003
SKS

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER